



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

FEB 08 2013

The Honorable Jim McDermott
House of Representatives
Washington, D.C. 20515-4707

Dear Mr. McDermott:

Thank you for your letter of December 6, 2012, cosigned by Representative Tom Marino, expressing support of the Memorandum of Understanding between the Food and Drug Administration (FDA or the Agency) and the America Society of Nephrology, establishing the Kidney Health Initiative (KHI).

As your letter notes, up to 26 million Americans have kidney disease. As noted by Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research, in today's complex world of new product development, establishing a deeper knowledge of disease states and forging multi-disciplinary collaborations have become essential to finding safe and effective new therapies. KHI is a powerful example of this successful formula and demonstrates our shared commitment to improving the health and safety of patients with kidney disease.

Thank you, again, for contacting us concerning this matter. The same letter has been sent to Mr. Marino.

Sincerely,

A handwritten signature in blue ink that reads "Michele Mital".

Michele Mital
Acting Associate Commissioner
for Legislation